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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,512	12/05/2005	Yutaka Mizushima	TAK003 P330	3849

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
08/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,512	MIZUSHIMA ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *9-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/7/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 are pending. Claims 3 and 7 were amended in a preliminary amendment submitted on December 5, 2005. Claims 9-12 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restrictions

Applicant's election of Group I in the reply filed on June 29, 2009 is acknowledged. Applicants' requested "reconsideration" of the restriction requirement is understood to be a traversal of the restriction requirement based on the lack of unity standard. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The abstract of the disclosure is objected to because the abstract consists of more than 15 lines of text and more than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 7 is objected to because of the following informalities: the comma on line 2 of said claim after "comprising" is improper and should be removed. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is vague and indefinite because it recites the phrase, "in that porous apatite derivative has a zinc substitution rate or zinc content rate of 0.1 to 2.0." This phrase is unclear because it refers to a rate of substitution (i.e. a process step), and does not clearly convey the amount of zinc required to be present in the claimed microparticles It appears that Applicants are attempting to describe product-by-process steps alluded to in parent claim 3; however, as written, claim 4 does not clearly describe what amount of zinc the final apatite derivative is required to contain. Thus, an ordinary skilled artisan would be unable to ascertain the metes and bounds of the claimed microparticles.

Claim Rejections - 35 USC § 102

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Mizushima et al. (WO 04/000270) (Mizushima-WO), wherein US 2006/0093670 is being used as the English language equivalent, or alternatively claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Mizushima et al. (US 2006/0093670) (Mizushima-US).

The applied reference has a common inventor (i.e. Mizushima) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Applicants claim sustained release microparticles comprising a drug other than human growth hormone and a porous apatite derivative, wherein in some embodiments the microparticles also comprise a water-soluble bivalent metal compound (e.g. $ZnCl_2$).

Mizushima discloses compositions comprising **porous sustained-release hydroxyapatite (i.e. an apatite derivative) microparticles comprising (i) a drug, (ii) human**

serum protein, (iii) a mucopolysaccharide, and zinc ions, wherein said composition may be in a form suitable for parenteral administration (e.g. subcutaneous or intramuscular) (title; abstract; claims 1, 7, and 11). The preparation of porous sustained-release hydroxyapatite microparticles described above and comprising **zinc acetate as the source of zinc ions and BDNF (i.e. a drug) or interferon-alpha (i.e. a drug)** are exemplified in Examples 1 and 2, respectively ([0053]-[0054]).

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 7-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Lin (US 2004/0180091).

Applicants claim sustained release microparticles comprising a drug other than human growth hormone and a porous apatite derivative, wherein the microparticles are intended for parenteral administration (e.g. subcutaneous or intramuscular injection).

Lin discloses **porous microspheres having a pore size ranging from 1 nm to 1,000 nm (claim 24) made from a composite matrix consisting of (i) poorly-crystalline calcium deficient carbonate apatite (cHA), (ii) biocompatible polymeric materials, and (ii) biologically or therapeutically active agents**. The term, "porous apatite derivative," reads on porous cHA. Microspheres read on microparticles. Regarding claims 7-8, the claimed preparation does not contain any additional required components aside from the microparticles of

claim 1. Because the microspheres disclosed by Lin are porous, have the same size (i.e. microspheres are microparticles), and comprise the same components required by Applicants' claim 1, Lin's microspheres inherently exhibit sustained release properties and must be suitable for parenteral administration as well.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7, 11, 18, and 24-25 of copending Application No. 10/516,122 (copending '122). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of sited claims claim sustained-release porous microparticles comprising an apatite derivative and each also

claim embodiments wherein the microparticles comprise divalent metal ions. Independent claim 1 of the instant application has been described above. Independent claim 1 of copending '122 claims a sustained-release composition comprising porous hydroxyapatite microparticles having pores charged with a biologically active drug, a human serum protein, a mucopolysaccharide, and an embolized divalent metal ion. Claim 24 of copending '122 claims essentially the same composition of claim 1 of copending '122.

The primary difference between the cited claims is that the claims of copending '122 recite porous microparticles containing additional required components and the claims of copending '122 are drawn to a composition. Because the only component recited in the claims of copending '122 are the porous microparticles, these claims effectively claim porous microparticles. Thus, the claims of copending '122 represent a species of the claimed microparticles of the instant application. A species anticipates a genus and anticipation is the epitome of obviousness. Regarding the recitation in claims 2 and 5-6 that the microparticles comprise a water-soluble bivalent compound, such as zinc chloride or zinc acetate, these limitations represent obvious modifications of the claims 7 and 25 of copending '122, because the only way to obtain microparticles comprising zinc ions is for these microparticles to comprise a zinc compound. This position is supported, for example, by Example 1 in the specification of copending '122, which exemplifies the preparation of porous microparticles comprising zinc ions by the addition of zinc acetate. Thus, it is reasonable to conclude that the microparticles comprising zinc ions necessarily comprise a zinc compound. The selection of a source of zinc ions, such as zinc acetate, is thus prima facie obvious. It is proper to turn to an application's disclosure as a dictionary to understand the scope of what is meant by a term in a

claim and/or to ascertain what constitutes an obvious modification. This position is supported by the courts. See *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-8 *prima facie* obvious over claims 1, 5, 7, 11, 18, and 24-25 of copending Application No. 10/516,122 (copending '122).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-8 are rejected. Claims 9-12 are withdrawn from consideration. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, ~10:00-6:00 and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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